

510(k) Summary

JUN 21 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number: K131213

1. Date of submission: April 26, 2013

2. Submitter

SonoScape Company Limited

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3. Proposed Device Identification

Trade/Proprietary Name: S40 Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System and Transducers

Classification:

21 FR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 FR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Classification Panel: Radiology

Device Class: II

4. Legally Marketed Predicate Device

SonoScape Company Limited, Diagnostic Ultrasound System, Model S6 has been cleared by FDA through 510(k) No.K112602 (Decision Date – November 07, 2011).

5. Device Description

The SonoScape S40 Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

6. Intended Use Statement

The SonoScape S40 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Transducer Information is shown in the table 1.

Table 1 Transducer Information

| No. | Probe | Type | Frequency Range | Intended Use |
|-----|-------|--------------------|-----------------|-------------------------------|
| 1 | C344 | curved Array | 2.0-5.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 2 | C353 | curved Array | 2.0-6.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 3 | C322 | curved Array | 2.0-6.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 4 | VC6-2 | curved Array | 2.0-6.0 MHz | Fetal / Abdominal/ Ob/GYN |
| 5 | 6V1 | Micro-curved Array | 4.0-8.0 MHz | Trans-rectal Trans-vaginal |
| 6 | 6V3 | Micro-curved | 5.0-9.0 MHz | Trans-rectal |

| No. | Probe | Type | Frequency Range | Intended Use |
|-----|-------|--------------|-----------------|---|
| | | Array | | Trans-vaginal |
| 7 | L741 | Linear Array | 5.0-10.0 MHz | Small Organ (breast, thyroid, testes) Musculo-skeletal (Conventional) Peripheral vessel |
| 8 | L742 | Linear Array | 5.0-12.0 MHz | Small Organ (breast, thyroid, testes) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel |
| 9 | L752 | Linear Array | 5.0-12.0 MHz | Small Organ (breast, thyroid, testes) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel |
| 10 | 2P2 | Phase Array | 1.0-5.0 MHz | Abdominal Cephalic(neonatal and adult) Cardiac (neonatal and adult) |
| 11 | 3P1 | Phase Array | 1.0-5.0 MHz | Abdominal Cephalic(neonatal and adult) Cardiac (neonatal and adult) |
| 12 | 5P2 | Phase Array | 3.0-8.0 MHz | Pediatric Neonatal Cephalic Cardiac Pediatric |
| 13 | 8P1 | Phase Array | 4.0-12.0 MHz | Pediatric Neonatal Cephalic Cardiac Pediatric |

7. Testing

Laboratory testing was conducted to verify that the S40 system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment".

Tab 2 Applicable Safety Standards

| Standards No. | Standards Title | Version | Date |
|----------------|---|------------------------|---------------------|
| IEC 60601-1 | Medical Electrical Equipment - Part1. General Requirements for Safety | 1988+A1: 1991+A2: 1995 | 10/31/2005 |
| IEC 60601-1-2 | Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests | 2007 | 03/01/2007 |
| IEC 60601-2-37 | Medical Electrical Equipment, Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment | 2007 | 08/01/2007 |
| NEMA UD 2 | Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3 | 2004 | 01/01/2004 (R 2009) |
| NEMA UD3 | Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment | 2004 | 01/01/2004 (R 2009) |
| ISO 10993-5 | Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity | 1999 | 05/15/1999 |
| ISO 10993-10 | Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity | 2002 | 09/01/2002 |

8. Clinical Test:

No clinical testing was required.

9. Comparison Table

The differences between the S40 and the predicate device S6 in almost every part are listed in the tables below.

Table 3 Intended Use Comparison

| ID | Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|--------------|---|--|--------|
| 1 | Intended Use | The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn. | The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology. | Same |

Table 4 General Comparison

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|-------------------------|---|---|---------------|
| 2 | Classification Name | Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer | Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer | Same |
| 3 | Product Code | 90-IYN/90-IYO/90-ITX | 90-IYN/90-IYO/90-ITX | Same |
| 4 | Regulation Number | 892.1550/892.1560/892.1570 | 892.1550/892.1560/892.1570 | Same |
| 5 | Panel | Radiology | Radiology | Same |
| 6 | Class | II | II | Same |
| 7 | Probe Type & Connectors | L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L752 Linear Array, 5.0-12.0 MHz | L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz | SE Analysis 1 |

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|------------------|---|---|--------|
| | | C344 Curved Array, 2.0-5.0 MHz C322 Curved Array, 2.0-6.0 MHz C353 Curved Array, 2.0-6.0 MHz / | C344 Curved Array, 2.0-5.0 MHz C362 Curved Array, 2.0-6.0 MHz C611 Micro-curved Array, 4.0-8.0 MHz | |
| | | VC6-2 Curved Array, 2.0-6.0 MHz | VC6-2 Curved Array, 2.0-6.0 MHz | |
| | | 6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz | 6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz | |
| | | 2P2 Phased Array, 1.0-5.0 MHz 3P1 Phased Array, 1.0-5.0 MHz 5P2 Phased Array, 3.0-8.0 MHz 8P1 Phased Array, 4.0-12.0 MHz | 2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz | |
| | | Multi-port connector connects 4 transducers | Multi-port connector connects 2 transducers | |
| 8 | Acoustic Track | TRACK 3 | TRACK 3 | Same |

Table 5 Functions Comparison

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|------------------|--|--|---------------|
| 9 | Design | Based on an embedded Linux operating system. | Based on an embedded Linux operating system. | Same |
| | | Based on a 128 channel full digital beam former. | Based on a 64 channel full digital beam former. | SE Analysis 2 |
| | | Autocorrelation for color processing and FFT for pulse | Autocorrelation for color processing and FFT for pulse | Same |

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|--------------------|--|--|---------------|
| 10 | Operation Controls | and CW Doppler processing. | and CW Doppler processing. | |
| | | Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz. | Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz. | Same |
| | | Cine play back capability | Cine play back capability | Same |
| | | Image file archive | Image file archive | Same |
| | | Software upgrade with USB flash drive. | Software upgrade with USB flash drive. | Same |
| | | Digital Scan Converter 800×600 | Digital Scan Converter 800×600 | Same |
| | | With touch panel | With full keyboard | SE Analysis 3 |
| 10 | Operation Controls | TGC 8 slider | TGC 8 slider | Same |
| | | Depth Range: 3 to 32 cm | Depth Range: 3 to 32 cm | Same |
| | | Image sector size: 32 lines to full B (512 lines) | Image sector size: 32 lines to full B (256 lines) | SE Analysis 4 |
| | | Image Sector position: Steering within full maximum | Image Sector position: Steering within full maximum | Same |
| | | B orientation flip :L/R key with marking on the screen | B orientation flip :L/R key with marking on the screen | Same |
| | | B Dynamic range control: preset 14 curves over 140 dB | B Dynamic range control: preset 14 curves over 140 dB | Same |
| | | Gray Scale Control: 7 Settings | Gray Scale Control: 7 Settings | Same |
| | | Focal Number: 12 focal zone setting | Focal Number: 12 focal zone setting | Same |
| | | B persistence: 0-95% | B persistence: 0-95% | Same |
| | | Image Processing: Smoothing, edge enhancement | Image Processing: Smoothing, edge enhancement | Same |
| | | PW sweeping speed 2,4,6,8 sec over display | PW sweeping speed 2,4,6,8 sec over display | Same |
| | | PW Wall filter setting:16 settings,25 to 750 HZ | PW Wall filter setting:16 settings,25 to 750 HZ | Same |
| | | PW sample volume:0.5 to 20mm | PW sample volume:0.5 to 20mm | Same |
| | | PW/B update: with UPDATE key | PW/B update: with UPDATE key | Same |
| | | PW cursor steering: Steer soft key | PW cursor steering: Steer soft key | Same |
| | | PW angle correction:0 to 80 degree user control | PW angle correction:0 to 80 degree user control | Same |

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|-------------------|---|---|--------|
| | | PW spectrum dynamic range:10 preset curve over 15-48 dB | PW spectrum dynamic range:10 preset curve over 15-48 dB | Same |
| | | Spectrum baseline shift and invert | Spectrum baseline shift and invert | Same |
| | | Color ROI setting: trackball and set key to control size and position | Color ROI setting: trackball and set key to control size and position | Same |
| | | Color steering on flat probe: ± 20 , $\pm 16,0$ | Color steering on flat probe: ± 20 , $\pm 16,0$ | Same |
| | | Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF | Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF | Same |
| | | Color priority-B priority soft menu | Color priority-B priority soft menu | Same |
| | | Color Packet size: preset per Exam, horizontal, vertical, off | Color Packet size: preset per Exam, horizontal, vertical, off | Same |
| | | Zoom adjustable | Zoom adjustable | Same |
| | | Freeze control: Toggling freeze key | Freeze control: Toggling freeze key | Same |
| | | Cine control: step, play backward, play continuously | Cine control: step, play backward, play continuously | Same |
| 11 | Operation Mode | B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode | B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode | Same |
| 12 | Display Modes | Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging. | Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging. | Same |
| 13 | Measurement Items | Distance; area; circumference; calipers; volume, velocity, HR, PI, RI, Cardiac, OB/GYN, Urology, Vascular and small | Distance; area; circumference; calipers; volume, velocity, HR, PI, RI, Cardiac, OB/GYN, Urology, Vascular and small | Same |

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|------------------|----------------------------------|----------------------------------|--------|
| | | part package | part package | |
| 14 | Cine Loop | Automatic review/ manual review | Automatic review/ manual review | Same |
| | | Review speed can be adjusted | Review speed can be adjusted | Same |

Table 6 Specifications Comparison

| ID | Comparison Items | Proposed Device SonoScape S40 | | | Predicate Device SonoScape S6 | | | Remark | |
|----|----------------------|----------------------------------|-----------------------------|--|----------------------------------|-----------------------------|-------------|---------------|--|
| 15 | Power Supply | Voltage: 110-127/220-240 VAC | | Voltage: 110-240 VAC | | | | SE Analysis 5 | |
| | | Frequency: 50/60 Hz | | Frequency: 50/60 Hz | | | | | |
| | | Power Consumption: 450VA | | Power Consumption: 110-240V AC, 2.7-1.2A | | | | | |
| 16 | Operating Condition | Temperature: 10~40°C | | Temperature: 10~40°C | | | | Same | |
| | | Relative humidity: 30~75% | | Relative humidity: 30~75% | | | | Same | |
| | | Air pressure: 700hPa ~1060hPa | | Air pressure: 700hPa ~1060hPa | | | | Same | |
| 17 | Storage Condition | Temperature: -20~55°C | | Temperature: -20~55°C | | | | Same | |
| | | Relative humidity: 20~90% | | Relative humidity: 20~90% | | | | Same | |
| | | Air pressure: 700hPa ~1060hPa | | Air pressure: 700hPa ~1060hPa | | | | Same | |
| 18 | Screen Size | 18.5 inch Widescreen LCD monitor | | 15 inch Widescreen LCD monitor | | | | SE Analysis 6 | |
| 19 | Measurement Accuracy | Parameter | Value range | Error range | Parameter | Value range | Error range | | |
| | | Display depth | Max 32.9 cm; (Probe depend) | ±3% | Display depth | Max 32.9 cm; (Probe depend) | ±3% | Same | |
| | | Distance | 0~31.0 cm | ±3% | Distance | 0~31.0 cm | ±3% | Same | |
| | | Area | Max. ≥855 cm ² | ±7% | Area | Max. ≥855 cm ² | ±7% | Same | |
| | | Angle | 10~193° | ±3% | Angle | 10~193° | ±3% | Same | |
| | | Circumference | 200 cm | ±3% | Circumference | 200 cm | ±3% | Same | |
| | | Volume | Max. 25000 cm ³ | ±10% | Volume | Max. 25000 cm ³ | ±10% | Same | |
| | | M-Mode time | 2,4,6,8 S | ±1% | M-Mode time | 2,4,6,8 S | ±1% | Same | |
| | | Heart Rate | 8 ~ 1000 beats/sec | ±3% | Heart Rate | 8 ~ 1000 beats/sec | ±3% | Same | |
| | | Slope | 1300 cm/s | ±3% | Slope | 1300 cm/s | ±3% | Same | |

| ID | Comparison Items | Proposed Device SonoScape S40 | | | Predicate Device SonoScape S6 | | | Remark |
|----|------------------|---|----------------|-----------------|---|----------------|-----------------|---------------|
| | | Velocity (PW) | 0.04-2940 cm/s | Angle ≤60°, ≤5% | Velocity (PW) | 0.04-2940 cm/s | Angle ≤60°, ≤5% | |
| 20 | Acoustic Output | Velocity (CW) | 0.12-3795 cm/s | Angle ≤60°, ≤5% | Velocity (CW) | 0.13-3529 cm/s | Angle ≤60°, ≤5% | SE Analysis 7 |
| | | Velocity (Color) | 1-298 cm/s | Angle ≤60°, ≤5% | Velocity (Color) | 2-226 cm/s | Angle ≤60°, ≤5% | |
| | | Track 3: MI, TIS, TIC, TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max | | | Track 3: MI, TIS, TIC, TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max | | | |

Table 7 Safety Comparison

| ID | Comparison Items | Proposed Device SonoScape S40 | Predicate Device SonoScape S6 | Remark |
|----|---------------------------------|-------------------------------------|-------------------------------------|--------|
| 21 | Electrical Safety | -IEC 60601-1 | -IEC 60601-1 | Same |
| 22 | EMC | -IEC 60601-1-2 | -IEC 60601-1-2 | Same |
| 23 | Performance | -IEC 60601-2-37 | -IEC 60601-2-37 | Same |
| 24 | Biocompatibility | -ISO 10993-5, -ISO 10993-10 | -ISO 10993-5, -ISO 10993-10 | Same |
| 25 | Level of Concern Of Software | Moderate level of concern system | Moderate level of concern system | Same |

SE Analysis 1:

Probe Type & Connectors, Compare to the predicate device, the proposed device is with different probe type or frequency, such as L752, C353 etc. But no new intended use is added and all of them comply with IEC 60601-2-37; And the proposed device has 4 probe connection ports and the predicate device has 2 probe connection ports, but both of them comply with IEC 60601-1 and IEC 60601-1-2, therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 2:

The proposed device is based on a 128 channel full digital beam former and the predicate device is 64, but the 128 channel is better than 64 channel in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 3:

The predicate device is with full keyboard and the proposed device is not, but both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 4:

The proposed device is with 512 lines image sector size and the predicate device is 256, but the 512 lines is better than 256 lines in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 5

The Power Supply of the proposed device and the predicate device are 110-127/220-240 VAC, 450VA and 110-240VAC, 2.7-1.2A respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

SE Analysis 6

The screen size of the proposed is larger than that of the S6. This difference is considered to have no effect on effectiveness and safety.

SE Analysis 7:

The proposed device and the predicate device are with different measurement accuracy in Velocity (CW/ Color), but the proposed device is better. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Discussion of Substantially Equivalent

The subject device has same intended use, similar product design, and same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design

principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

10. Substantially Equivalent Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S40 Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

SonoScape Company Limited
% Ms. Toki Wu
Yizhe Building, Yuquan Road, NanShan
Shenzhen, Guangdong 518051
P.R. CHINA

Re: K131213

Trade/Device Name: S40 Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, and ITX
Dated: April 26, 2013
Received: May 2, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the S40 Digital Color Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P2 Phase Array
8P1 Phase Array
C344 Curved Array
VC6-2 Curved Array

3P1 Phase Array
6V1 Micro-curved Array
C353 Curved Array
L741 Linear Array
L752 Linear Array

5P2 Phase Array
6V3 Micro-curved Array
C322 Curved Array
L742 Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

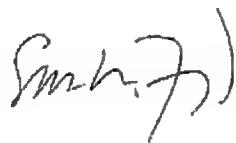
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shing Chun Benny Lam, Ph.D. at (301) 796-9328.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number: K131213

Device Name: S40 Digital Color Doppler Ultrasound System

Indications for Use: The SonoScape S40 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Smith)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131213

Diagnostic Ultrasound Indications for Use Form

System: SonoScape S40

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | N | N | N | | N | N | Note 1 | Notes 2,4,5 |
| | Abdominal | N | N | N | | N | N | Note 1 | Notes 2,4,5 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Small Organ (specify) | N | N | N | | N | N | Note 1 | Notes 2,4,6 |
| | Neonatal Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Adult Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Trans-rectal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Trans-vaginal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Musculo-skeletal (Superficial) | N | N | N | | N | N | Note 1 | Notes 2,4 |
| Cardiac | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | N | N | N | | N | N | Note 1 | Notes 2,4,5 |
| | Cardiac Adult | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Cardiac Pediatric | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| Peripheral Vessel | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| | Peripheral vessel | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Other (specify) | | | | | | | | |

N = new Indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: 2P2 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|---------|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CW D | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Adult Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Cardiac Pediatric | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color

Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: 3P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|----------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Adult Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| Cardiac | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| | Cardiac Adult | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Cardiac Pediatric | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Intravascular(Cardiac) | | | | | | | | |
| Peripheral Vessel | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; PWD; B/Power Doppler/PWD

Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: 5P2 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|----------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color

Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: 8P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|----------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | N | N | N | N | N | N | Note 1 | Notes 2,3,4 |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color

Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Trans-vaginal | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color

Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Trans-vaginal | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| Cardiac | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| Peripheral Vessel | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral Vessel | Other (specify) | | | | | | | | |
| | Peripheral vessel | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& Other | Fetal | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Abdominal | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| Cardiac | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| Peripheral Vessel | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C353 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Abdominal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| Cardiac | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| Peripheral Vessel | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C322 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| General (TRACK 1 ONLY) | Clinical Application Specific (TRACKS 1 & 3) | Mode of Operation | | | | | | | |
|------------------------------|--|-------------------|---|-----|-----|------------------|---------------------------------|--------------------------------|-------------------------------|
| | | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other ^a Combined | Other ^a Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Abdominal | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| Cardiac | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| Peripheral Vessel | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------------------|-------------------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other ^a Combined | Other ^a Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | P | P | P | | P | P | Note 1 | Notes 2,4,5 |
| | Abdominal | P | P | P | | P | P | Note 1 | Notes 2,4,5 |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| Cardiac | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | P | P | P | | P | P | Note 1 | Notes 2,4,5 |
| Peripheral Vessel | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| Peripheral Vessel | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | | |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color

Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging& Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | P | P | P | | P | P | Note 1 | Notes 2,4,6 |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | P | P | P | P | P | P | Note 1 | Notes 2,4 |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| Cardiac | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| Peripheral Vessel | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | P | Note 1 | Notes 2,4 |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | Mode of Operation | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|
| | | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging& Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative Specify | | | | | | | |
| | Intra-operative Neuro | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (specify) | P | P | P | | P | P | Note 1 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | |
| Cardiac | Musculo-skeletal (Conventional) | P | P | P | | P | P | Note 1 |
| | Musculo-skeletal (Superficial) | P | P | P | | P | P | Note 1 |
| | Intravascular | | | | | | | |
| | Other (Ob/GYN) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| Peripheral Vessel | Intravascular(Cardiac) | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | |
| Peripheral Vessel | Intra-cardiac | | | | | | | |
| | Other (specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | P | Note 1 |
| | Other (specify) | | | | | | | Notes 2,4 |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L752 Linear Array
 Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|---------------------------------|--------------------|-------------------|
| General (TRACK 1 ONLY) | Specific (TRACKS 1 & 3) | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Other* Combined | Other* Specify |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (specify) | N | N | N | | N | N | Note 1 | Notes 2,4,6 |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Musculo-skeletal (Superficial) | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN) | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | N | N | N | | N | N | Note 1 | Notes 2,4 |
| | Other (specify) | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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